

pet-
J006 Rec'd PCT/PTO 11 MAY 2005

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/519,121
	Filing Date	September 15, 2003
	First Named Inventor	Marc K. HELLERSTEIN
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	9 + 54 Refs.	Attorney Docket Number 416272003900

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	1. PTO/SB/08a/b (5 pages)
<input checked="" type="checkbox"/> Information Disclosure Statement (Supplemental, 3 pages)	<input type="checkbox"/> CD, Number of CD(s) _____	2. 54 Cited References
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Landscape Table on CD	3. Return Receipt Postcard
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name	MORRISON & FOERSTER LLP (Customer No. 20872)	
Signature	<i>Michael R. Ward</i>	
Printed name	Michael R. Ward	
Date	May 10, 2005	Reg. No. 38,651

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV731514177US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: May 11, 2005

Signature:

Laura Tsang

(Laura Tsang)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV731514177US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: May 11, 2005

Signature:

Laura Tsang
(Laura Tsang)

Patent
Docket No. 416272003900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Marc K. HELLERSTEIN

Serial No.: 10/519,121

Filing Date: September 15, 2003

For: METHODS FOR MEASURING RATES
OF REVERSE CHOLESTEROL
TRANSPORT IN VIVO, AS AN INDEX
OF ANTI-ATHEROGENESIS

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.

- ☒ **Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.**
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
- ☐ A fee is required. A check in the amount of __ is enclosed.
- ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

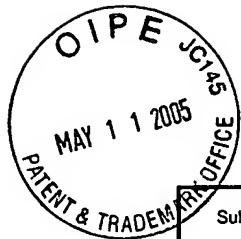
The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 416272003900.

Dated: May 10, 2005

Respectfully submitted,

By Michael R. Ward
Michael R. Ward
Registration No.: 38,651
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
(415) 268-6237



ALTERNATIVE TO PTO/SB/08a/b (06-03)

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/519,121
				Filing Date	September 15, 2003
				First Named Inventor	Marc K. HELLERSTEIN
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	416272003900

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-11/094,387	FD 3-29-2005	Hellerstein	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	2.	WO-05/033652-A2	04-14-2005	Hellerstein		

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	3.	"New Diagnostic Technique Could Help Treat AIDS," Agence France-Presse, Dow Jones News/Retrieval, Feb. 17, 1998, pp. 1-2.	
	4.	ADAMI, H.O. et al. (1995) "The Aetiology and Pathogenesis of Human Breast Cancer" <i>Mutation Research</i> 333: 29-35	
	5.	ANDERSON, R.W. et al. (1998) "Direct HIV Cytopathicity Cannot Account for CD4 Decline in AIDS in the Presence of Homeostasis: A Worst-Case Dynamic Analysis" <i>J. AIDS and Human Retrovirology</i> 17:245-252	
	6.	ASHER, E. et al. (1995) "Evaluation of Cell Death in EBV-Transformed Lymphocytes Using Agarose Gel Electrophoresis, Light Microscopy and Electron Microscopy" <i>Leukemia and Lymphoma</i> 19:107-119	
	7.	BLAU, K. and HALKET, J. eds. (1993) <u>Handbook of Derivatives for Chromatography</u> , 2nd Edition, John Wiley & Sons Ltd., England	
	8.	BUCY, R.P. et al. (1998) "Analysis of Lymph Node Biopsies in HIV Infected Patients Before and After HAART" <i>Abstract, 5th Conference on Retroviruses and Opportunistic Infections, Session 66</i> 519:177	
	9.	CALDWELL, K.A. et al. (1993) "Quantification of Peptide Isotopomer Abundances and Determination of Protein (sic) Turnover Rates by Using Mass Isotopomer Distribution Analysis" <i>Abstract, 41st Annual Amer. Society Mass Spectrometry on Mass Spectrometry</i> , p. 331a.	
	10.	CASSELLA, C.R. et al. (1997) "Mechanisms of Lymphocyte Killing by HIV" <i>Current Opinion in Hematology</i> 4:24-31	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

sf-1926215

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/519,121
				Filing Date	September 15, 2003
				First Named Inventor	Marc K. HELLERSTEIN
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	2	of	5	Attorney Docket Number	416272003900

11.	CESAR, D. et al. (1998) "Direct Measurement of CD4+ and CD8+ T Cell Proliferation Rates in Vivo in AIDS Patients Using a Stable Isotope-Mass Spectrometric Technique" <i>Abstract, 5th Conference on Retroviruses and Opportunistic Infections</i> , Chicago Illinois
12.	COHEN, A. et al. (1983) "Purine and Pyrimidine Metabolism in Human T Lymphocytes," <i>J. Biol. Chem.</i> 258(20):12334-12340
13.	COHEN, J. (1998) "Failure Isn't What It Used to Be...But Neither is Success" <i>Science</i> 279:1133-1134
14.	CONNERS, M. et al. (1997) "HIV Infection Induces Changes in CD4+ T-Cell Phenotype and Depletions Within the CD4+ T-Cell Repertoire that are not Immediately Restored by Antiviral or Immune-Based Therapies" <i>Nature Medicine</i> 3(5):533-540
15.	CRAIN, P.F. (1990) "Preparation and Enzymatic Hydrolysis of DNA and RNA for Mass Spectrometry," <i>Meth. Enz.</i> 193:782-790
16.	DEEKS, S. et al. (1998) "Viral Load and CD4+ T Cell Changes in Patients Failing Potent Protease Inhibitor Therapy" <i>Abstract, 5th Conference on Retroviruses and Opportunistic Infections, Session 53</i> , 419:158
17.	DIMITROV, D.S. et al. (1995) Scientific Correspondence, <i>Nature</i> 375:194-195
18.	GOROCHOV, G. et al. (1998) "Perturbation of CD4+ and CD8+ T-Cell Repertoires During Progression to AIDS and Regulation of the CD4+ Repertoire During Antiviral Therapy," <i>Nature Medicine</i> 4(2):215-221
19.	GRATZNER, H.G. (1982) "Monoclonal Antibody to 5-Bromo-and 5-Iododeoxyuridine: A New Reagent for Detection of DNA Replication" <i>Science</i> 218:474-475
20.	HELLERSTEIN, M.K. et al. (1997) "T Cell Turnover in HIV-1 Disease," <i>Immunity</i> 7:583-589 (Nov. 1997).
21.	JAMES, J.S. (1998) "Clinical Implications of Virological Failure: Interview with Steven Deeks, M.D., San Francisco General Hospital," <i>AIDS Treatment News</i> , 289:6-7
22.	LIPKIN, M. (1987) "Proliferation and Differentiation of Normal and Diseased Gastrointestinal Cells" In <i>Physiology of the Gastrointestinal Tract</i> , L.R. Johnson ed., Raven Press, New York, pp. 255-284
23.	MARGOLICK, J.B. et al. (1995) "Failure of T-cell Homeostasis Preceding AIDS in HIV-1 Infection," <i>Nature Medicine</i> , 1(7):674-680
24.	MCCLOSKEY, J.A. (1990) "Electron Ionization Mass Spectra of Trimethylsilyl Derivatives of Nucleosides," <i>Meth. Enz.</i> 193:825-841
25.	MCCUNE, J.M. (1997) "Thymic Function in HIV-1 Disease," <i>Seminars</i>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/519,121
				Filing Date	September 15, 2003
				First Named Inventor	Marc K. HELLERSTEIN
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	3	of	5	Attorney Docket Number	416272003900

		<i>in Immunology</i> -9:397-404	
26.		MCLEAN, A.R. et al. (1995) "In Vivo Estimates of Division and Death Rates of Human T Lymphocytes," <i>Proc. Natl. Acad. Sci USA</i> 92:3707-3711	
27.		MEIER, P.R. et al. (March 1981) "Rates of Protein Synthesis and Turnover in Fetal Life," <i>Am J Physiol.</i> , 240(3):E320-E324	
28.		MELLORS, J.W. et al. (1995) "Quantitation of HIV-1 RNA in Plasma Predicts Outcome after Seroconversion," <i>Ann. Intern. Med.</i> 122:573-579	
29.		MELLORS, J.W. et al. (1996) "Prognosis in HIV-1 Infection Predicted by the Quantity of Virus in Plasma," <i>Science</i> , 272:1167-70	
30.		MICHIE, C.A. et al. (1992) "Lifespan of Human Lymphocyte Subsets Defined by CD45 Isoforms," <i>Nature</i> 360:264-265	
31.		MOSIER, D.E. (1995) "CD4 _{sup} + Cell Turnover," <i>Nature</i> 375:193-194	
32.		MURALI-KRISHNA, K. et al. (1998) "Counting Antigen-Specific CD8 T Cells: A Reevaluation of Bystander Activation during Viral Infection," <i>Immunity</i> 8:177-187	
33.		OYAIKU, N. et al. (1995) "Role of Apoptosis in HIV Disease Pathogenesis," <i>J. of Clinical Immunology</i> 15(5):217-231	
34.		PALMER, L.D. et al. (1997) "Telomere Length, Telomerase Activity, and Replicative Potential in HIV Infection: Analysis of CD4+ and CD8+ T Cells from HIV-discordant Monozygotic Twins," <i>J. Experimental Medicine</i> 185(7):1381-1386	
35.		PAPAGEORGOPOULOS, C. et al.(1993) "Toward the Measurement of Protein Synthesis by Mass Isotopomer Distribution Analysis (MIDA):Resolution of Isotopomers in a [d.sub.3]-Leucine Enriched Synthetic Oligopeptide Using Electrospray/Quadrupole Mass Spectrometry (ESI/MS)," <i>Abstract, Federation of American Societies for Experimental Biology</i> 1022:A177	
36.		PATTON, G.M. et al. (July 1979) "Measurements of Fatty Acid Synthesis by Incorporation of Deuterium from Deuterated Water," <i>Biochemistry</i> , 18(14):3186-3188	
37.		PERELSON, A.S. et al.(1996) "HIV-1 Dynamics in Vivo: Virion Clearance Rate, Infected Cell Life-Span, and Viral Generation Time," <i>Science</i> 271:1582-1586	
38.		PERELSON, A.S. et al.(1997) "Decay Characteristics of HIV-1-Infected Compartments During Combination Therapy," <i>Nature</i> 387:188-191	
39.		REICHARD, P. (1978) "From Deoxynucleotides to DNA Synthesis,"	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/519,121
				Filing Date	September 15, 2003
				First Named Inventor	Marc K. HELLERSTEIN
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	4	of	5	Attorney Docket Number	416272003900

		<i>Federation Proceedings</i> 37(1):9-14	
40.	REICHARD, P. (1988)	"Interactions Between Deoxyribonucleotide and DNA Synthesis," <i>Ann. Rev. Biochem.</i> 57:349-374	
41.	ROEDERER, M. (July 1995)	"T-Dell Dynamics of Immunodeficiency," <i>Nature Medicine</i> 1(7):621-622	
42.	SAWADA, S. et al. (1995)	"Comparison of Autoradiography, Liquid Scintillation Counting and Immunoenzymatic Staining of 5-bromo-2'-deoxyuridine for Measurement of Unscheduled DNA Synthesis and Replicative DNA Synthesis in Rat Liver," <i>Mutation Research</i> 344:109-116	
43.	SCALISE, K. (Feb. 11-17, 1998)	"Tracking T-Cells in AIDS Patients: A Safe Reliable Method of Measuring Human Cell Generation Rates," <i>Berkeleyan</i> , p. 3.	
44.	SHIGENAGA, M.K. et al. (1994)	"Assays of Oxidative DNA Damage Biomarkers 8-Oxo-2'-deoxyguanosine and 8-Oxoguanine in Nuclear DNA and Biological Fluids by High-Performance Liquid Chromatography with Electrochemical Detection," <i>Methods in Enzymology</i> 234:16-33	
45.	SPRENT, J. et al. (1995)	"CD4+ Cell Turnover," <i>Nature</i> 375:194	
46.	TRABER, P.G. et al. (1991)	"Isolation of Intestinal Epithelial Cells for the Study of Differential Gene Expression Along the Crypt-Villus Axis," <i>Am. J. Physiol.</i> 260:G895-G903	
47.	WADKE, M. et al. (July 1973)	"Fatty Acid Synthesis by Liver Perfused with Deuterated and Tritiated Water," <i>Biochemistry.</i> , 12(14):2619-2624	
48.	WAIN-HOBSON, S. (1995)	"Virological Mayhem," <i>Nature</i> 373:102	
49.	WALDEMAN, F.M. et al. (1991)	"A Comparison Between Bromodeoxyuridine and 3 H Thymidine Labeling in Human Breast Tumors," <i>Modern Path.</i> 4(6):718-722	
50.	WEI, X et al. (1995)	"Viral Dynamics in Human Immunodeficiency Virus Type 1 Infection," <i>Nature</i> 373:117-122	
51.	WOLTHERS et al. (1998)	"Rapid CD4+ T-Cell Turnover in HIV-1 Infection: a Paradigm Revisited," <i>Immunol. Today</i> 19(1):44-48	
52.	WOLTHERS, K.C. et al. (1996)	"T Cell Telomere Length in HIV-1 Infection: No Evidence for Increased CD4+ T Cell Turnover," <i>Science</i> 274:1543-1547	
53.	WOOD, H.G. et al. (1963)	"Estimation of Pathways of Carbohydrate Metabolism," <i>Biochemische Zeitschrift</i> 338:809-847	
54.	ZHANG, Z-Q. et al. (Feb. 1998)	"Kinetics of CD4+ T Cell Repopulation	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/519,121
				Filing Date	September 15, 2003
				First Named Inventor	Marc K. HELLERSTEIN
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	5	of	5	Attorney Docket Number	416272003900

		of Lymphoid Tissues after Treatment of HIV-1 Infection," <i>Proc. Natl. Acad. Sci. USA</i> 95:1154-1159	
	55.	ZILVERSMIT, D.B. et al. (1943) "On the Calculation of `Turnover Time` and `Turnover Rate` from Experiments Involving the Use of Labeling Agents," <i>J. of General Physiology</i> 26(3):325-331	

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--